Novocure Announces the EF-14 Phase III Clinical Trial of Tumor Treating Fields in Patients with Newly Diagnosed Glioblastoma has been Terminated at the Interim Analysis due to Early Success

Data presented today as a late-breaking abstract at the Society for Neuro-Oncology 2014 Annual Meeting in Miami demonstrated the EF-14 trial met its primary endpoint of progression-free survival and secondary endpoint of overall survival in a planned interim analysis

The EF-14 trial Independent Data Monitoring Committee recommended terminating the trial early and allowing all control patients to receive Tumor Treating Fields

St. Helier, Jersey – November 15, 2014 – Novocure™, a commercial stage oncology company, announced today that Tumor Treating Fields (TTFields) delivered by the NovoTTF™-100A System in combination with standard-of-care temozolomide chemotherapy extended both progression-free survival (PFS) and overall survival (OS) compared to temozolomide alone in patients with newly diagnosed glioblastoma (GBM). The late-breaking, EF-14 Phase III trial data were presented today at the Society for Neuro-Oncology (SNO) 2014 Annual Meeting in Miami, Florida by Dr. Roger Stupp, Professor and Chairman, Department of Oncology and Director, University Hospital Cancer Center, University of Zurich, Zurich, Switzerland.

The pre-specified, interim analysis of EF-14 trial data was conducted on the first 315 patients, representing approximately 50 percent of the targeted study population. The data show that:

- Patients treated with TTFields together with temozolomide demonstrated a significant increase in progression free survival compared to temozolomide alone (median PFS of 7.1 months compared to 4.0 months, respectively, hazard ratio=0.63, p=0.001).

- Patients treated with TTFields together with temozolomide demonstrated a significant increase in overall survival compared to temozolomide alone (median OS of 19.6 months compared to 16.6 months, respectively, hazard ratio=0.75, p=0.034).

- The percentage of patients alive at 2 years in the TTFields together with temozolomide arm was 43% compared to 29% in the temozolomide alone arm.

Based on the interim analysis results, the Independent Monitoring Committee (IDMC) for the EF-14 trial recommended that the trial be stopped early and that Novocure provide access to TTFields for patients on the temozolomide alone arm. Novocure is in discussions with the United States (U.S.) Food and Drug Administration (FDA) regarding the regulatory pathway for TTFields in newly diagnosed GBM.

“These results are spectacular,” said Dr. Roger Stupp, M.D., Director of the University Hospital Cancer Center at the University of Zurich, Zurich, Switzerland and EF-14 Principal Investigator. “A new standard of care for patients suffering from glioblastoma is born.”

“The results presented today by Dr. Roger Stupp set the stage for establishing TTFields therapy as a major modality in solid tumor cancer treatment,” said William Doyle, Executive Chairman of Novocure. “Achieving statistically-significant and clinically meaningful results in both overall survival and progression-free survival is a fantastic outcome for the GBM patients we serve. I extend my sincere thanks to patients and investigators in the EF-14 trial and to the many supporters who have helped us achieve this important milestone.”

“We are very pleased with the EF-14 results and are working closely with the FDA to make TTFields therapy available to newly diagnosed glioblastoma patients as soon as possible,” said Asaf Danziger, Novocure’s Chief Executive Officer. “Novocure remains committed to the research and development of TTFields for a variety of solid tumor cancer types.

About Glioblastoma
Glioblastoma (GBM) is the most common form of primary brain cancer with approximately 10,000 patients diagnosed each year in the U.S. Overall survival with standard of care temozolomide chemotherapy alone is approximately 15 months.

About the NovoTTF-100A System
The NovoTTF-100A System is a portable, non-invasive medical device designed for continuous use by patients. *In vitro* and *in vivo* studies have shown that the NovoTTF-100A System slows and reverses tumor growth by inhibiting mitosis, the process by which cells divide and replicate. The NovoTTF-100A System creates a low intensity, alternating electric field within a tumor that exerts physical forces on electrically charged cellular components, preventing the normal mitotic process and causing cancer cell death. The NovoTTF-100A System is experimental for the treatment of newly diagnosed glioblastoma in the U.S. and is limited by law to investigational use only.

The NovoTTF-100A System has received marketing approval in the U.S. under the brand name Optune™ for recurrent GBM. The NovoTTF-100A System is a CE Marked device cleared for sale in the European Union, Switzerland, Australia and Israel.

Approved Indication
The U.S. FDA has approved Optune for use as a treatment for adult patients (22 years of age or older) with histologically-confirmed GBM, following histologically– or radiologically-confirmed recurrence in the supra-tentorial region of the brain after receiving chemotherapy. The device is intended to be used as monotherapy, and is intended as an alternative to standard medical therapy for GBM after surgical and radiation options have been exhausted. Patients should only use Optune under the supervision of a physician properly trained in use of the device. Full prescribing information is available at www.optune.com/safety or by calling toll free 1-855-281-9301.

About Novocure
Novocure is a private Jersey Isle oncology company pioneering a novel therapy for solid tumors called TTFields. Novocure US operations are based in Portsmouth, NH and New York, NY. Additionally, the company has offices in Switzerland and Japan and a research center in Haifa, Israel. For additional information about the company, please visit www.novocure.com.

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